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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,892	12/29/2004	Tetsuya Sakata	10921.267USWO	9700
52835	7590	10/05/2007		
HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902 MINNEAPOLIS, MN 55402-0902			EXAMINER NAQI, SHARICK	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/519,892

Applicant(s)

SAKATA ET AL.

Examiner

Sharick Naqi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-19 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 11 and 16-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Examiner acknowledges the amendment filed on July 18, 2007

#### ***Claim Objections***

Claim 4 is objected to because of the following informalities:

Line 1 of claim 4 states, "lancet supplying according to claim 1". Examiner suggests that it be changed to "lancet supplying unit according to claim 1."

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 3-10 and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kijima et al. US Patent Publication No. 2003/0144608.**

1. A lancet supplying unit comprising a case (box 63c) having a closed bottom and a closable open top (box 63c), a lancing member housed in the case (lancet 2), a sensor housed in the case (sensor 1) and provided separately from the lancing member, and a

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supporter (box 63c and grooves 630a-c) detachably supporting each of the lancing member and the sensor in the housing, wherein the case is temporarily attached to a lancing apparatus for supplying the lancing member and the sensor to the lancing apparatus, and wherein the lancing member and the sensor remain attached to the lancing apparatus even after the case is detached from the lancing apparatus.

(Paragraph 0288, Figures 19, 20 (a) and 20(b) shown that the lancet and sensor are attached to the lancing apparatus and removed from the case.)

3. The lancet supplying unit according to claim 1, wherein the sensor is held by a sensor holder (measuring device 11 has guides 17, case 11b and lancet adjustment button 16), and wherein, when lancing of a skin is performed by utilizing the lancing member, the sensor holder engages the lancing member to control lancing depth in the skin.

(Paragraph 0188 and 0192. The adjustment button 16 is used to control amount of projection of the lancet.)

4. (Currently Amended) The lancet supplying according to claim 1, wherein the lancing member includes a needle (needle 2a), and wherein the lancing unit further comprises a cap for covering the needle (protection cover 3), the cap being detachable from the lancing member (Fig 1(a) and Fig 1(b). Paragraph 0168).

5. The lancet supplying unit according to claim 4, wherein the lancing member includes

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a body (lancet 2) holding the needle, and wherein the cap is integrally formed on the body. (Fig. 6 (a))

6. The lancet supplying unit according to claim 5, wherein a boundary portion between the cap and the body has a structure which causes a stress to be concentrated on the boundary portion more than on other portions of the cap and the body. (paragraph 0215, Fig. 6 (a) and Fig. 6 (b))

7. The lancet supplying unit according to claim 6, wherein the boundary portion has a constricted configuration. (paragraph 0215, Fig. 6 (a) and Fig. 6 (b))

8. The lancet supplying unit according to claim 4, wherein the lancing member is supported by the supporter via the cap. (Fig .19. The protective cover 3 which is attached to the lancing member is supported by box 63c via lower groves 630a.)

9. The lancet supplying unit according to claim 8, wherein the caps formed separately from the supporter and supported by the supporter. (Fig .19. The protective cover 3 which is attached to the lancing member is supported by box 63c via lower groves 630a.)

10. The lancet supplying unit according to claim 9, wherein the supporter includes a portion for fitting to a part of the cap to hold the cap in a standing posture. (Fig .19. The

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protective cover 3 which is attached to the lancing member is supported by box 63c via lower grooves 630a. It holds the cap in a standing posture.)

12. The lancet supplying unit according to claim 4, wherein the case includes a tubular portion for accommodating the cap together with the lancing member and the sensor. (Fig .19. The protective cover 3 which is attached to the lancing member is supported by box 63c via lower grooves 630a.)

13. The lancet supplying unit according to claim 12, further comprising a lid for closing the open end of the case. (Fig 19, element 63a)

14. The lancet supplying unit according to claim 4, wherein a direction in which the sensor is detachable from the supporter corresponds to a direction in which the cap is detachable from the lancing member. (Figs 1 (a) and 1 (b), 19, 20 (a) and 20 (b). The sensor is detachable from the box (supporter) in a longitudinal direction away from the box and protective cover 3 is detachable from the lancet in a longitudinal direction away from the lancet. It is the Examiner's position that this meets the claimed limitation.)

15. The lancet supplying unit according to claim 4, wherein the sensor is detachably supported by the cap. (Fig .19. The protective cover 3 is attached to lancet 2 which is attached to sensor 1 therefore sensor is supported by the cap)

***Allowable Subject Matter***

Claims 11 and 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

In regards to claim 8, the limitation that the cap in the lancet supplying unit of claim 4 is integrally formed on the supporter is not found in the applied prior art.

In regards to claim 16, the following limitation is not found in the prior art, "wherein the cap is supported by the supporter while being interposed between the lancing member and the sensor in a first direction in which the needle of the lancing member extends, the cap being movable in a second direction crossing the first direction to avoid overlapping with a holder retaining the sensor in the first direction." Claims 17-19 are allowable based on their dependency on claim 16.

Claim 29 is allowed over the prior art for the reasons given in the previous office action.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 and 3-19 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharick Naqi whose telephone number is 571-272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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